

Amendment(s) to the Claims

The following listing of claims replaces all prior versions and listings of claims in the present application:

Listing of Claims:

1 (currently amended): A throat, mouth and/or gum sprayable pharmaceutical preparation in the form of an aqueous solution comprising:

a ~~nonsteroidal~~ non-steroidal ~~antiinflammatory~~ anti-inflammatory drug (NSAID) also having analgesic activity;

a biologically compatible buffer consisting essentially of an organic amine selected from at least one of D-glucamine, meglumine, trometamol (tris buffer) and a mixture thereof, in a quantity suitable for buffering the pH of the preparation within the range specified below;

a pH within a range from 6.5 to 8.0; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen.

2 (currently amended): Use of a sprayable pharmaceutical preparation ~~for~~ in the manufacture of an ~~antiinflammatory~~ anti-inflammatory agent for treating the mouth, throat and/or gums, wherein the pharmaceutical ~~composition~~ preparation is in the form of an aqueous solution comprising:

a ~~nonsteroidal~~ non-steroidal anti-inflammatory drug (NSAID) also having analgesic activity;

a biologically compatible buffering organic amine provided with a free or monosubstituted amino group or a mixture thereof, in a quantity suitable for buffering the pH of the preparation within the range specified below;

a pH within a range from 6.5 to 8.0; and

pharmaceutical grade water;

wherein the NSAID is flurbiprofen and the biologically compatible buffering organic amine is D-glucamine, meglumine, trometamol (tris buffer) or a mixture thereof.

3 (currently amended): A pharmaceutical preparation ~~or use~~ according to claim 1 ~~or claim 2~~, wherein the flurbiprofen is in the form of a racemate or one of its enantiomers selected from R-(-) flurbiprofen and S-(+) flurbiprofen.

4 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of claims~~ claim 1 to 3, ~~which comprises~~ wherein the flurbiprofen is present in a quantity of from about 1.5 mg/ml to about 8.0 mg/ml, ~~preferably about 2.5 mg/ml~~.

5 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of the preceding claims~~ claim 1, ~~which has a~~ wherein the pH ~~of from~~ is between about 7.0 to and about 7.5.

6 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of the preceding claims~~ claim 1, ~~which comprises~~ wherein D-glucamine is present in a quantity of from about 0.35 mg/ml to about 1.12 mg/ml; meglumine is present in a quantity of from about 0.40 mg/ml to about 2.4 mg/ml; and/or trometamol is present in a quantity of from about 0.10 mg/ml to about 0.75 mg/ml.

7 (currently amended): A pharmaceutical preparation ~~or use according to any one of the preceding claims~~ claim 1, ~~which comprises wherein~~ the buffer is present in a quantity suitable for buffering the pH of the solution within the range of ~~from~~ between about 7.0 ~~to~~ and about 7.5.

8 (currently amended): A pharmaceutical preparation ~~or use according to any one of the preceding claims~~ claim 1, ~~which further comprises~~ comprising:

a mild disinfectant; and/or

one or more preservatives; and

wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride, optionally in a quantity of from about 1.0 mg/ml to about 6.0 mg/ml, optimally ~~of~~ about 5.0 mg/ml, and (ii) glycyrrhizic acid or a salt thereof, optionally in a quantity of from about 0.8 mg/ml to about 1.2 mg/ml, optimally ~~of~~ about 1.0 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate, optionally in a quantity of from about 0.25 mg/ml to about 1.15 mg/ml, (ii) propyl p-hydroxybenzoate, optionally in a quantity of from about 0.03 mg/ml to about 0.15 mg/ml, (iii) disodium calcium edetate, optionally in a quantity of from about 0.1 mg/ml to about 1.0 mg/ml, and (iv) sodium benzoate, optionally in a quantity of from about 0.2 mg/ml to about 5.0 mg/ml.

9 (currently amended): A pharmaceutical preparation ~~or use according to any one of the preceding claims~~ claim 1, ~~which further comprises~~ comprising at least one further ingredient selected from the group consisting of a viscosity agent, a sweetening agent,

a fluidising agent, a thickening agent, a colouring agent and a natural essence of flavouring agent.

10 (currently amended): A pharmaceutical preparation ~~or use~~ according to claim 9, wherein the further ingredient is selected from the group consisting of at least one of glycerol, sorbitol, xylitol, ethyl alcohol, castor oil 40 polyethoxylate, saccharin sodium, acesulfame potassium, mint essence, natural mint flavour, natural peach flavour and patent blue V-E131, E-124.

11 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of claims claim 1 to 9,~~ further comprising xylitol[.].

12 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of the preceding claims claim 1,~~ wherein the preparation is in the form of a mouthwash for spraying, preferably with a dispensed volume for each unit dose of from about 100 microlitres (0.1 ml) to about 300 microlitres (0.3 ml), ~~preferably of about 200 microlitres (0.2 ml).~~

13 (currently amended): A pharmaceutical preparation ~~or use~~ according to ~~any one of the preceding claims claim 1,~~ wherein the buffer is D-glucamine, meglumine, or a mixture thereof.

14 (currently amended): A packaged pharmaceutical preparation ~~containing the pharmaceutical preparation defined in any one of claims according to claim 1 to 13,~~ wherein the preparation is equipped with a dosing pump.

15 (currently amended): A process for the production of the pharmaceutical preparation defined in ~~any one of claims claim 1 to 13, which comprises~~ comprising:

- (i) dissolving preservative(s) in a solution;
- (ii) dissolving the selected NSAID in water or a water/ethyl alcohol mixture and buffering with the organic amine to the specified pH value;
- (iii) adding any auxiliary ingredients to the solution of step (i), and mixing the solution of step (i) with the solution of NSAID and organic amine from step (ii);
- (iv) making up to volume (or weight) with water, if necessary, and adjusting the pH to the prescribed value with addition of organic amine.

16 (new): A pharmaceutical preparation according to claim 1, wherein the flurbiprofen is present in a quantity of about 2.5 mg/ml.

17 (new): A pharmaceutical preparation according to claim 12, wherein the dispensed volume for each unit dose is about 200 microlitres (0.2 ml).

18 (new): The use according to claim 2, wherein the flurbiprofen is in the form of a racemate or one of its enantiomers selected from R-(-) flurbiprofen and S-(+) flurbiprofen.

19 (new): The use according to claim 2, wherein the flurbiprofen is present in a quantity of from about 1.5 mg/ml to about 8.0 mg/ml.

20 (new): The use according to claim 2, wherein the flurbiprofen is present in a quantity of about 2.5 mg/ml.

21 (new): The use according to claim 2, wherein the pH of the solution is between about 7.0 and about 7.5.

22 (new): The use according to claim 2, wherein D-glucamine is present in a quantity of from about 0.35 mg/ml to about 1.12 mg/ml; meglumine is present in a quantity of from about 0.40 mg/ml to about 2.4 mg/ml; and/or trometamol is present in a quantity of from about 0.10 mg/ml to about 0.75 mg/ml.

23 (new): The use according to claim 2, wherein the buffer is present in a quantity suitable for buffering the pH of the solution within the range of between about 7.0 and about 7.5.

24 (new): The use according to claim 2, wherein the pharmaceutical preparation further comprises:

a mild disinfectant; and/or

one or more preservatives; and

wherein:

the mild disinfectant comprises at least one of (i) cetylpyridinium chloride, optionally in a quantity of from about 1.0 mg/ml to about 6.0 mg/ml, optimally about 5.0 mg/ml, and (ii) glycyrrhizic acid or a salt thereof, optionally in a quantity of from about 0.8 mg/ml to about 1.2 mg/ml, optimally about 1.0 mg/ml; and

the preservative comprises at least one of (i) methyl p-hydroxybenzoate, optionally in a quantity of from about 0.25 mg/ml to about 1.15 mg/ml, (ii) propyl p-hydroxybenzoate, optionally in a quantity of from about 0.03 mg/ml to about 0.15 mg/ml,

(iii) disodium calcium edetate, optionally in a quantity of from about 0.1 mg/ml to about 1.0 mg/ml, and (iv) sodium benzoate, optionally in a quantity of from about 0.2 mg/ml to about 5.0 mg/ml.

25 (new): The use according to claim 2, wherein the pharmaceutical preparation further comprises at least one further ingredient selected from the group consisting of a viscosity agent, a sweetening agent, a fluidising agent, a thickening agent, a colouring agent and a natural essence of flavouring agent.

26 (new): The use according to claim 25, wherein the further ingredient is selected from the group consisting of at least one of glycerol, sorbitol, xylitol, ethyl alcohol, castor oil 40 polyethoxylate, saccharin sodium, acesulfame potassium, mint essence, natural mint flavour, natural peach flavour and patent blue V-E131, E-124.

27 (new): The use according to claim 2, wherein the pharmaceutical preparation further comprises xylitol.

28 (new): The use according to claim 2, wherein the preparation is in the form of a mouthwash for spraying, preferably with a dispensed volume for each unit dose of from about 100 microlitres (0.1 ml) to about 300 microlitres (0.3 ml).

29 (new): The use according to claim 28, wherein the dispensed volume for each unit dose is about 200 microlitres (0.2 ml).

30 (new): The use according to claim 2, wherein the buffer is D-glucamine, meglumine, or a mixture thereof.

31 (new): The use according to claim 2, wherein the pharmaceutical preparation is supplied with a dosing pump.